K091069

JUN - 1 2009

Medacta International

Traditional 510(k) Summary

Manufacturer: MEDACTA International SA
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Contact Person: Ms. Natalie J. Kennel
Consultant
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Date Prepared: May 27, 2009

DEVICE INFORMATION

Trade/Proprietary Name: Medacta Bone Screws
Common Name: Bone Screws
Classification Name: Screw, Fixation, Bone
21 CFR 888.3560
Class II
Device Product Code: JWH

Predicate Devices: K011719 Plus Cancellous Bone Screws
K081023 Evolis Total Knee System

Product Description:
The Medacta Bone Screws are intended to provide additional bone fixation of the tibial components of the Evolis Total Knee System. The Medacta Bone Screws have a thread diameter of 6.5 mm. The Medacta Bone Screws come in six lengths from 20 mm to 45 mm in increments of 5 mm.

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The Medacta Bone Screws are made of titanium alloy (Ti6-Al4-V) according to ISO5832-3:1996, Implants for Surgery – Metallic materials – Part 3: Wrought titanium 6-aluminum 4-vanadium alloy.

Indications for Use:
The Medacta Bone Screws are intended to provide additional bone fixation of the tibial components of the Evolis Total Knee System.

The Evolis Total Knee System is designed for cemented use in total knee arthroplasty, if there is evidence of sufficient sound bone to seat and support the components.

This knee replacement system is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis
- avascular necrosis of femoral condyle
- post traumatic loss of joint configuration
- primary implantation failure.

Performance Testing
No performance standards applicable to this device have been adopted under Section 514 of the Food, Drug and Cosmetic Act. Performance testing of the Medacta Bone Screws was conducted in accordance with international standards and FDA guidance documents. The bone screws were tested and found to be in conformance with ASTM F543-07 Standard Specification and Test Methods for Metallic Bone Screws.

Comparison with Predicate Device
The Medacta Bone Screws have the same indications for use and contraindications as the Evolis predicate device system with which they are intended to work. The Medacta Bone Screws are made of the same type of material as the Plus predicate device. They come in the same thread diameter as the Plus predicate and come in lengths within the range of the predicate device screw lengths.

Conclusion:
The data and information provided in this submission support the conclusion that the Medacta Bone Screws are substantially equivalent to its predicate devices, Plus Cancellous Bone Screws with respect to technological characteristics. The Medacta Bone Screws have the same indications for use as the Evolis Total Knee System with which they are intended to work. Actual device performance as tested conforms to applicable standards and FDA guidance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MEDACTA International SA
% Ms. Natalie J. Kennel
Consultant
13721 Via Tres Vista
San Diego, California 92129

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Re: K091069
Trade/Device Name: Medacta Bone Screws
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH, HWC
Dated: May 29, 2009
Received: June 28, 2009

Dear Ms. Kennel:

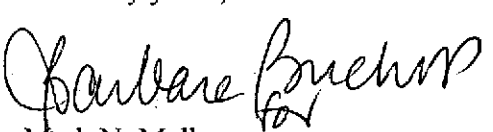
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091069

Indications for Use Statement

510(k) Number (if known): K091069

Device Name: Medacta Bone Screws

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- post traumatic loss of joint configuration.
- primary implantation failure.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K091069